Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2011-0009]

Implementation of FSIS Traceback and Recall Procedures for Escherichia coli O157:H7 Positive Raw Beef Product

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice: Response to comments; planned implementation for traceback and recall procedures.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing that it will implement new traceback procedures when FSIS or another Federal or State agency finds raw ground beef or bench trim presumptive positive for Escherichia coli O157:H7. FSIS is also announcing that it will begin requesting an establishment to recall product if an establishment was the sole supplier of beef manufacturing trimmings source materials for ground beef product that FSIS or another Federal or State agency finds positive for E. coli O157:H7, evidence suggests that the contamination most likely occurred at the supplier establishment, and a portion of the product from the originating source lot produced by the supplier establishment was sent to other establishments. FSIS is also clarifying circumstances when the Agency will ask suppliers of product used in bench trim to recall the product. FSIS is also announcing the availability

of updated guidance documents. Finally, FSIS is responding to comments on the May 7, 2012, Federal Register notice, "Changes to FSIS Traceback, Recall Procedures for Escherichia coli O157:H7 Positive Raw Beef Product, and Availability of final Compliance Guidelines".

DATES: Beginning [INSERT DATE 60 DAYS AFTER PUBLICATION], FSIS Enforcement, Investigations, and Analysis Officers (EIAOs) will conduct traceback investigations described in this notice. Additionally, beginning [INSERT DATE 60 DAYS AFTER PUBLICATION], FSIS will implement new recall procedures described in this notice.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On May 7, 2012, FSIS published a Federal Register notice (77 FR 26725) announcing new traceback procedures that it intended to implement when FSIS or other Federal or State agencies find a presumptive positive for Escherichia coli (E. coli) O157:H7 in raw ground beef or bench trim. FSIS explained that these new procedures would enable FSIS to better determine whether the establishments that produced the source materials

for contaminated product have produced other product that may not be microbiologically independent from the contaminated product. The Agency also announced its intention to request that an establishment recall product if the establishment was the sole supplier of beef manufacturing trimmings source materials for ground product that FSIS or other Federal or State agencies find positive for E. coli O157:H7, evidence suggests that contamination most likely occurred at the supplier establishment, and a portion of the product from the originating source lot from the supplier establishment was sent to other establishments (77 FR 26725). Finally, this notice announced the availability of compliance guidelines concerning establishment sampling for Shiga toxin-producing E. coli (STEC) organisms or virulence markers and compliance guidelines for STEC sampled and tested labeling claims.

FSIS has summarized and responded to the comments on the Federal Register notice and guidance below. In response to the comments, FSIS has not made any significant changes to the policies, procedures, or guidance announced in 2012. However, FSIS has updated the policies, procedures, and guidance to reflect the changes that apply to E. coli O157:H7 and would appropriately apply to non-O157 STEC.

On September 20, 2011, FSIS declared six STEC organisms, in addition to E. coli O157:H7, adulterants in raw non-intact

beef product or raw intact beef product intended for use in raw non-intact beef product (76 FR 58157). On June 4, 2012, FSIS started testing beef manufacturing trimmings for these six non-O157 STEC organisms. FSIS is gathering information to assess the economic effects of testing for the non-O157 STECs in raw ground beef components and ground beef. As noted in the May 31, 2012 Federal Register, when the Agency completes the updated analysis, FSIS will announce its availability and request comments on the analysis (77 FR 31976). As FSIS also stated in the May 31, 2012 Notice, the Agency will then assess comments and make any necessary changes before finalizing the economic analysis and before making a determination on expanding FSIS testing to include ground product and raw ground beef components other than beef manufacturing trimmings. Below, FSIS has discussed how FSIS would implement the traceback and recall policies based on non-O157 STEC positive results in ground beef and bench trim should FSIS start testing these products for the adulterant non-O157 STEC.

FSIS will use high event period (HEP) criteria in determining whether a systemic breakdown of process control at a slaughter establishment led to cross-contamination between multiple production lots. A systemic breakdown of process control and the resulting contamination would create insanitary conditions that may affect the disposition of intact lots of

beef in addition to beef manufacturing trimmings and could lead to more product becoming adulterated than the product found positive for the pathogen. As is discussed below, FSIS has revised the FSIS Compliance Guideline For Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers (http://www.fsis.usda.gov/wps/wcm/connect/e0f06d97-9026-4e1e-a0c2-1ac60b836fa6/Compliance_Guide_Est_Sampling_STEC_0512.pdf?MOD=AJPERES) to include the six additional adulterant STEC such that if an establishment's sample testing shows that it has experienced a HEP, then the establishment has likely experienced a HEP for non-O157 STEC as well as for E. coli O157:H7. Similarly, FSIS has revised the Compliance Guideline for E. coli O157:H7 Sampled and Tested Claims for Boneless Beef Manufacturing Trimmings (Trim) (http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index/!ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbwMDIHQ08842MTDy8_YwMgYqCASWYG_paEbUEFYoL-3s7OBhZ8xkfpxAEcDQvq9iLDAqMjX2TddP6ogsSRDNzMvLV8_Ijk_tyAnMzEvOVU3vTQzJbUYKJ6SWqEfrh-F10B_E3QFWHwMUYDbSwW5oRFVPmnBnumKigBJZmxC/#Ecoli) to address the data that FSIS would need to see to approve labels bearing

statements that product has been sampled and tested for non-O157 STEC, in addition to E. coli O157:H7.

Final Traceback Policy

FSIS will implement the traceback procedures announced in the May 7, 2012 Federal Register on [insert 60 days from publication]. Under these new traceback procedures, Enforcement, Investigations, and Analysis Officers (EIAOs) will conduct traceback investigations at establishments that produced the E. coli O157:H7 presumptive positive product and at suppliers that provided source materials for the ground beef or bench trim that FSIS or other Federal or State agencies find presumptive positive. These traceback investigations will begin as soon as possible in response to presumptive positive results and supplier information from the producing establishment. During these investigations, EIAOs will gather relevant information about the production of the product, including use of antimicrobials and prevention of cross-contamination, sanitary conditions, and relevant purchase specifications.

Furthermore, as part of their traceback investigations, EIAOs will review slaughter establishment test results to determine whether the establishment has experienced a HEP. HEPs in beef manufacturing trimmings at slaughter establishments are periods in which the establishment experiences a high percentage of positive results for E. coli O157:H7 or Shiga

toxin-producing E. coli (STEC) organisms or virulence markers in beef manufacturing trimmings samples from production lots containing the same source materials. In this situation, the beef manufacturing trimmings were produced from one or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., shift).

There are two types of HEP that may indicate out-of-control situations in the establishment's production process. A HEP may indicate an event in which some specific occurrence or event causes a clustering of STEC organisms or virulence markers that indicate contamination in product, or a HEP may mean that a systemic breakdown of the slaughter dressing operation has occurred and has created an insanitary condition that may be applicable to all parts of the beef carcass (e.g., primal cuts in addition to the beef manufacturing trimmings and other raw ground beef and patty components). If the establishment has developed its own supportable HEP criteria, then the EIAOs will determine whether it has experienced a HEP based on the establishment's HEP criteria and will determine whether the establishment's HEP criteria are appropriately supported. Accordingly, FSIS recommends that as part of their supporting documentation for their hazard analysis (9 CFR 417.5(a)), establishments document the criteria they use to identify HEPs. If the establishment has not developed its own HEP criteria,

EIAOs will determine whether the establishment has experienced a HEP based on the FSIS criteria discussed below.

In the May 7, 2012 Federal Register, FSIS provided criteria for identifying a localized out-of-control event in which some specific occurrence caused a clustering of STEC contamination in product. The event would not indicate, necessarily, a severe or global systemic breakdown or inherent weakness of the process or food safety system. During a localized HEP, intact primal and subprimal cuts would not be affected if such cuts routinely undergo a complete pathogen reduction treatment on all exposed surfaces.

FSIS also provided criteria for identifying a systemic HEP that indicates a systemic breakdown or inherent weakness of the process or food safety system. Virtually all raw beef product produced during the period of the systemic HEP would likely be affected, regardless of whether antimicrobial treatments were applied such as to primal cuts.

FSIS is not making any changes to the HEP criteria described in the May 7, 2012 Federal Register. The final HEP criteria are:

1. For a local HEP: 3 or more STEC organism (or virulence marker) positive results out of 10 consecutive samples from production lots containing same-source materials; and

2. For a systemic HEP:

A. 7 or more STEC organism (or virulence marker) positive results out of 30 consecutive samples from production lots containing same-source materials.

B. At establishments that test more than 60 samples per day, from production lots containing same-source materials, the number of E. coli O157:H7 (or STEC organism or virulence marker) positive samples below within the samples tested in the table:

Unacceptable # Positives	Within Samples Tested
8	61
9	74
10	86
11	100
12	113
13	127
14	141
15	155
16	169
17	184
18	198
19	213
20	228

The above criteria are based on high degrees of confidence (establishing sufficient statistical evidence) that the process percentage exceeded 5 percent during some period. The 5 percent represents a value that is definitively higher than the expected percent positive found when an establishment is operating under good manufacturing practices. For the systemic HEP based on daily testing of more than 60 samples[1] and the local HEP

[1] FSIS selected a minimum of 60 samples for identifying daily HEP because the purpose of this criterion is to determine inconsistencies over a large amount of product produced during the day. The other two criteria apply for less

guidance, FSIS used close to 99 percent confidence for establishing sufficient statistical evidence.[2] For the systemic short-term HEP (based on 30 samples), FSIS selected about 99.95 percent confidence for asserting sufficient statistical evidence. The reason for this high degree of confidence is that FSIS wanted to have a short-term HEP criterion to help establishments identify periods of serious processing problems.

As FSIS explained in the May 7, 2012 Federal Register, based on all the information gathered during traceback investigations, EIAOs will present findings to the District Manager on which to determine whether adulterated product has entered commerce. The EIAO will also make recommendations concerning whether regulatory and enforcement actions are warranted. The District Manager will then determine whether adulterated product entered commerce; if it has, whether to contact the FSIS Recall Management and Technical Analysis Staff; and whether enforcement actions are appropriate.

At this time, EIAOs will perform the traceback procedures at establishments that produce raw ground beef products and bench trim products that FSIS or other Federal or State agencies find presumptive positive for E. coli O157:H7 and EIAOs will perform the traceback procedures at establishments that supply

product or shorter periods. FSIS identified the day-specific criterion for large volume establishments that often test more than 100 lots a day.

[2] For the local HEP involving 3 positive results from 10 samples, the confidence is 98.849644%, which FSIS considers to be close to 99%.

the source materials for these products. Should FSIS begin testing raw ground beef products and bench trim products for the six adulterant non-O157:H7 STEC, EIAOs would perform the traceback procedures at establishments that produce raw ground beef and bench trim products that FSIS or other Federal or state agencies find presumptive positive for any STEC organism that FSIS has declared to be an adulterant and EIAOs would perform traceback procedures at the supplying establishments that provided source materials for these products. These traceback procedures will allow FSIS to identify problems that occurred at the establishments that produced the non-O157 STEC positive product and at their suppliers on a timely basis.

As is explained in the May 7, 2012 Federal Register, most establishments use testing that includes an enrichment step followed by differential screening specific to STEC organisms, particularly E. coli O157:H7 or their associated virulence markers (77 FR 26728). Positive results during screening tests require further testing to detect E. coli O157:H7. If the establishment does not perform the additional testing, it should treat lots that test positive in screen tests as positive for E. coli O157:H7. Similarly, FSIS considers these results positive for STEC. STEC includes E. coli O157:H7 and the non-O157 STEC. If establishments test beef manufacturing trimmings for E. coli organisms and virulence markers rather than for specific STEC

organisms, and their results indicate that they have experienced a HEP based on the HEP criteria above, they will have likely experienced a HEP for E. coli O157:H7 and the non-O157 STEC. Therefore, during traceback investigations, if EIAOs determine that a slaughter establishment has experienced a HEP based on establishment results for beef manufacturing trimmings and based on the establishment's HEP criteria, or based on the FSIS HEP criteria, EIAOs will likely find that the establishment has experienced a HEP for non-O157 STEC in addition to E. coli O157:H7. The HEP criteria above would apply to non-O157 STEC, as well as E. coli O157:H7. The actions EIAOs will take in response to finding that an establishment has experienced a HEP for non-O157 STEC would be the same they would take in response to an E. coli O157:H7 HEP.

This notice imposes no new requirements for establishments related to HEPs. The new EIAO instructions and investigations are only intended to improve and expedite FSIS traceback procedures. As FSIS explained in the May 7, 2012 Federal Register, EIAOs do not conduct this type of traceback investigation now until they conduct Food Safety Assessments (FSAs). FSAs are scheduled approximately 30 days after the confirmed positive results become available, so FSAs are much later than the traceback investigations EIAOs will now conduct. As noted above, the new traceback investigations will begin as

soon as possible in response to presumptive positive results. Also, during FSAs, EIAOs do not ask all the focused questions that they will ask as part of this new procedure. Finally, EIAOs do not currently evaluate whether an establishment has experienced a HEP when performing an assessment (77 FR 26727).

Recall Policy

FSIS will also implement the recall procedures announced in the May 7, 2012 Notice on [insert 60 days from publication]. Under these procedures, FSIS will request that supplier establishments recall product if:

(1) FSIS or another Federal or State agency finds raw ground beef positive for E. coli O157:H7 at a grinding establishment;

(2) FSIS determines that E. coli O157:H7 introduction, such as cross-contamination, was unlikely to have occurred at the grinding establishment where the sample was taken (based on FSIS's assessment of the grinding establishment's handling practices);

(3) FSIS determines that the grinding establishment did not combine material from multiple source lots to create the lot of product that tested positive;

(4) After conducting traceback to identify the slaughter and beef manufacturing trimmings fabrication supplier that provided the sole source material, FSIS determines that

the supplier or downstream users split the implicated lot before sending it to the establishment where the positive sample was taken; and

(5) Some portion of the split lot sent to the grinder was sent into commerce for further processing into product that does not receive a full lethality treatment to eliminate E. coli O157:H7 in a federally inspected establishment.

If all of the foregoing occurs, FSIS will request the establishment to initiate a recall from the slaughter or beef manufacturing trimmings supplier establishment.

At this time, when the criteria listed above occur, the recall procedures will apply to suppliers of materials of raw ground beef products that FSIS or another Federal or State agency finds positive for E. coli O157:H7. Should FSIS begin testing ground beef for the six non-O157:H7 STEC that are adulterants, and the criteria listed above occur, those recall procedures would apply to suppliers of materials of raw ground beef products that FSIS or another Federal or State agency finds positive for any of the STEC organisms that FSIS has declared an adulterant. Contamination with any of these STEC organisms is most likely to occur at the supplying slaughter establishment, so it is appropriate that the Agency request a recall of any source materials still in commerce if a slaughter establishment

was the sole supplier of source materials for ground product that FSIS or another Federal or State agency finds positive for these STEC organisms. In addition, these recall policies and procedures are appropriate because STEC organisms are enteric pathogens. Therefore, contamination may occur during the slaughter process, from transfer of contamination from the hides, hooves, and gut of cattle. Contamination may occur through cross-contamination at the grinder; however, if there is no evidence of cross-contamination at the grinder, contamination most likely occurred at the slaughter or beef manufacturing trimmings establishment (77 FR 26728).

FSIS requested comments on costs that would result from this recall policy but did not receive specific comments on this issue. As explained in the May 7, 2012 Federal Register, had this recall policy been in place, FSIS may have requested 29 additional recalls in the two year period between January 1, 2009 and December 31, 2010, if suppliers had split their lots and sent source materials to other establishments in addition to the grinder where FSIS found the positive source material.[3] Any additional recalls under these circumstances are likely to better prevent the public from consuming adulterated product (77 FR 26727). Removing from commerce source materials that may be contaminated with STEC organisms is critically important. This

[3] Data are from the Policy Analysis Staff, the Office of Policy and Program Development, FSIS.

new recall policy will better protect the public from consumption of STEC contaminated product because it will better ensure that source materials that are contaminated with STEC organisms are removed from commerce.

FSIS samples beef manufacturing trimmings and most other raw ground beef components at the slaughter establishment. Therefore, if FSIS finds a positive in these products, it does not have to trace product back to a different slaughter supplier establishment because all the source materials are typically from the slaughter establishment that produced the positive product. However, FSIS samples "bench trim" at establishments that did not slaughter the cattle used to produce the source materials. Bench trim materials are materials that the receiving establishment uses as entire cuts to produce nonintact product or uses to derive trimmings for use in non-intact product.

When FSIS finds bench trim positive, FSIS does not typically request the recall of source materials from suppliers of the bench trim. In many cases, receiving establishments use primal or subprimal products as bench trim in their entirety to produce non-intact product. In this situation, the primal or subprimal products or trimmings would typically constitute an independent lot. Therefore, if FSIS finds the subprimal or primal product, or trim derived from the subprimal or primal

product, positive for E. coli O157:H7, FSIS would not typically request a recall from the supplier slaughter establishment because there would likely be no product to recall related to the primal or subprimal product. Also, based on FSIS's experience with bench trim sampling, bench trim is usually combined with multiple lots at the grinding establishment. So again, FSIS would not request a recall at the supplier establishment in this situation.

Bench trim is typically primal or subprimal product that the slaughter establishment did not intend for use in ground or other non-intact, raw product. Many slaughter establishments maintain information on their web sites or provide information to receiving establishments explaining that this product is not intended for grinding or use in other non-intact, raw product. However, receiving establishments may use some portion of the primal or subprimal product to produce non-intact, raw product. When they do so, many of these receiving establishments employ additional antimicrobial treatments to the primal or subprimal product or test the non-intact product or trimmings derived from the primal or subprimal product.

If FSIS finds the bench trim product positive and the slaughter establishment did not intend the primal or subprimal product to be used in non-intact product, the positive result does not necessarily represent a problem with the slaughter

establishment's food safety system. The slaughter establishment designated the primal or subprimal product for intact use and its food safety system likely addressed the hazards associated with intact product, rather than non-intact product.

However, should FSIS find bench trim positive, it would conduct the type of traceback investigation that is described in this notice and activities, including sampling and testing of primal and subprimal product, to verify that the establishment is meeting all HACCP requirements. In most cases, FSIS would not request that the slaughter establishment recall subprimal or primal product because the positive product was not intended for grinding or other non-intact use.

If data show that the slaughter establishment experienced a HEP, FSIS may request a recall. If FSIS finds that the slaughter establishment experienced a high event period and did not take action to reduce possible E. coli O157:H7 contamination in primal and subprimal products; that the slaughter establishment was the sole supplier for the bench trim; that contamination did not occur at the receiving bench trim establishment; and that the supplier co-mingled primal or subprimal cuts and then sent some of the same lot used to produce the bench trim that FSIS found positive to additional establishments, FSIS would ask the slaughter supplier establishment to recall the product.

Final Guidance

The May 7, 2012 Federal Register notice announced the availability of guidance, FSIS Compliance Guideline For Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers and Compliance Guideline for E. coli O157:H7 Sampled and Tested Claims for Boneless Beef Manufacturing Trimmings (Trim).

FSIS has revised the establishment sampling guidance to reflect the Agency's recent policy developments relating to the six adulterant non-O157 STECs. As is discussed above, most establishments generally test for pathogenic E. coli organisms and virulence markers rather than for specific STEC organisms. Therefore, the criteria that FSIS has provided in the guidance are general and would indicate that the establishment may be experiencing problems controlling any of the STEC organisms. The guideline is meant to help slaughter establishments develop and implement sampling and testing programs for STECs in beef manufacturing trimmings. The HEP guidance will be most useful to slaughter and fabrication establishments that manufacture 50,000 pounds or more of beef manufacturing trimmings daily because they are likely to conduct sufficient testing on same source beef manufacturing trimmings to be able to determine whether a HEP has occurred. Smaller volume slaughter and fabrication establishments can also use the HEP criteria in the

guidance, particularly those that take 10 or 30 samples. Non-slaughter establishments will not know whether problems with slaughter and dressing procedures have contributed to a HEP because they do not have the necessary information from the establishment that slaughtered the cattle. As is stated in the May 7, 2012 Federal Register, FSIS recommends that slaughter and fabrication establishments conduct sampling and testing of beef manufacturing trimmings at a frequency to find evidence of contamination surviving the slaughter and dressing operation (optimally every production lot) to best protect against adulterated product entering commerce. Establishment verification testing results on beef manufacturing trimmings are likely the best available information a slaughter establishment can use to determine the effectiveness of its slaughter and dressing operation (77 FR 26730).

FSIS also has revised the guidance to include a more detailed explanation of FSIS's HEP criteria, to make clear that establishments have flexibility in designing and supporting HEP criteria that is different from FSIS's HEP criteria, and to cite askFSIS as a resource for providing feedback to establishments on the design of HEP criteria that is different than FSIS's criteria.

FSIS recommends that establishments identify HEP criteria so they can determine whether they need to withhold product from

commerce when a HEP has occurred, because a HEP may indicate more widespread adulteration of product, beyond the product found positive. If establishments identify and respond to HEPs, they will minimize the chance that they will release adulterated product into commerce.

The sampled and tested claims guidance continues to provide information on the use of labels bearing an FSIS sketch approved E. coli O157:H7 sampled and tested claim on beef manufacturing trimmings. As is explained in the guidance, such special labeling claims are voluntary. An establishment may use such claims when it demonstrates that they are truthful and not misleading (9 CFR 317.8(a)). FSIS must approve such claims before the establishment may use them on labels (9 CFR 317.4(a)). FSIS has updated the guidance to recognize that establishments may want to submit a request for a labeling claim stating that product has been tested for the six adulterant non-O157:H7 STEC in addition to E. coli O157:H7. In the final guidance, FSIS has explained that the Agency would need to see the same type of information to approve sampled and tested claims for the other adulterant STEC organisms as it would need to see for sampled and tested claims concerning E. coli O157:H7.

As is explained in the May 7, 2012 Federal Register, this guidance document addresses label claims that are not intended to be displayed to consumers. FSIS may approve STEC organisms

sampled and tested claims on beef manufacturing trimmings that goes to, for example, a retailer who purchases the beef manufacturing trimmings for grinding. However, FSIS will not approve such a label claim for display to consumers because it may be misleading to them by suggesting that the end product is free of pathogens or may not need to be cooked thoroughly.

These labeling claims will provide receiving establishments or retailers with information regarding the sampling and testing of beef manufacturing trimmings for STEC organisms conducted by supplier establishments.

In order for a sampled and tested claim to be truthful and not misleading, the establishment making the claim must have incorporated into its HACCP systems measures designed to control for the STEC organisms addressed in the claim, and it must use sampling and testing methodologies that are designed to verify the effectiveness of those measures.

Plans for Future Study

The May 7, 2012 Federal Register notice stated that FSIS intends to conduct a study to test product from unopened containers or purge material (that is, remaining liquid, fat, and meat particles in containers or combo bins after beef manufacturing trimmings contents have been removed) from suppliers' product for E. coli O157:H7 to identify the source of E. coli O157:H7 positive raw ground beef when material from

multiple suppliers was used to create the sampled ground beef that FSIS has found positive for E. coli O157:H7.

Based on research, FSIS has concluded that source traceback by testing purge material cannot be accomplished because of the insufficiency of purge material available for testing purposes. At this time, FSIS is not starting a study on unopened packages to identify the source of E. coli O157:H7 positive raw ground beef when material from multiple suppliers was used to create the positive product. However, FSIS continues to believe that there may be merit in pursuing this type of study and will further explore whether analyzing unopened packages will assist FSIS to effectively identify suppliers of STEC positive products. Based on the results of these findings and the availability of necessary resources, FSIS may conduct this study in the future. FSIS will also continue to review available data related to multiple sources of ground beef products.

The May 7, 2012 Federal Register also stated that the Agency intends to determine whether it can make better use of the results of establishment (versus FSIS) testing for E. coli O157:H7 and other microorganisms and other data that establishments may collect to evaluate their sanitary dressing procedures. FSIS requested comment on how the Agency could better evaluate this data and use it to inform establishments that problems may be developing or to advise establishments to

take action to prevent the creation of insanitary conditions or the production of adulterated product in the future.

FSIS did not receive any comments on this issue. As noted in the May 7, 2012 Federal Register, inspection program personnel review establishment test results on a weekly basis (FSIS Directive 5000.2). FSIS intends to issue clarifying instructions to these personnel to look for increasing positive results that should be raised to the establishment's attention. For example, FSIS intends to revise the directive to instruct inspection program personnel to review the current results of any testing that the establishment has performed and compare them to the previous 30-days' results to determine whether an adverse trend is developing. Through this review and these clarifying instructions, FSIS personnel may be better able to advise establishments that problems may be developing. Similarly, establishments need to assess their verification testing results on a regular basis to ensure that their food safety systems effectively address hazards, including the STEC organisms.

Comments and Responses

FSIS received comments from five industry and consumer organizations in response to the May 7, 2012 Federal Register notice. Some consumer groups and industry supported the HEP

guidance. Following is a discussion of these comments and FSIS's responses.

Recall and Traceback Procedures

Comment: Two industry organizations commented that FSIS should not take samples of ground product produced from sole source materials for E. coli O157:H7 testing. To reduce costs of recalls, commenters suggested alternative FSIS sampling schemes. For example, one commenter stated that if the grinder combines product from multiple suppliers, FSIS should sample the product at the suppliers, not the grinder. Similarly, another commenter stated that if the product to be sampled is from a single source supplier, the sample should be collected at the supplying establishment, not the grinder.

Response: The Agency conducts routine sampling and testing for E. coli O157:H7 at all establishments that produce raw ground beef in order to ensure that all such establishments implement their own procedures to control for this pathogen. FSIS intends to continue collecting and testing samples at all establishments that produce raw ground beef product to verify that they have controls necessary to address E. coli O157:H7. As is noted above, FSIS may begin analyzing ground beef samples for non-O157 STEC in the future.

In response to these comments, FSIS is assessing whether it can routinely identify which grinders grind product from sole

suppliers on a consistent basis as a defined practice in their food safety system, and whether it would be appropriate to reduce Agency sampling and testing at such establishments.

FSIS will continue to collect samples at slaughter establishments that produce beef manufacturing trimmings for use in ground beef or other non-intact products and will continue to analyze these samples for E. coli O157:H7 and the adulterant non-O157 STEC. Similarly, FSIS will continue to collect samples of other raw ground beef components and to analyze them for E. coli O157:H7. In the future, FSIS may analyze samples of these products for the non-O157 STEC also. FSIS samples raw ground beef components to ensure that producers also have controls necessary to address STEC organisms. It is necessary that FSIS collect and analyze samples at both grinding processing establishments and at supplying establishments to verify that all establishments maintain adequate controls to address STEC organisms in their food safety systems.

Comment: An industry organization wanted to know how FSIS would complete the traceback review and asked what records would FSIS review to determine whether the recall criteria discussed in the Federal Register notice apply. Another industry organization stated that the EIAO's traceback methodology should be made available to all stakeholders.

Response: FSIS will review FSIS and establishment testing records, establishment lotting records, and supplier information to determine what product may be affected. FSIS will issue instructions to its field personnel on how to determine whether introduction of E. coli O157:H7 or cross-contamination likely occurred at the grinder. The instructions to the field personnel will include the criteria FSIS personnel are to use to determine whether product should be recalled. Information concerning Agency thinking for instructions to FSIS field personnel is at: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices/notices-2010/!ut/p/a1/jZBBC4JAEIV_Sz9AZlZF9GgLlpaKRLbtJZZabcFUVDr061PqYiU5p5nH93i8AQ4MeCnuKhedqkpRDDe3TpigRRyKQey5HvqR4aV2tCJokh44jgCHDECaxBtK0Y6Mmf6JcfGfP5gRoDchDXPgteiumiqzClgmL7IRhdbIXLWdbL4Vraw6dZYtsPei6UgQDsDHib1IhsSduQ4iA2PzE_jxkhcw3bm-7dlju3R85S6eyWLScQ!!/?1dmy&current=true&urile=wcm%3apath%3a/fsis-archives-content/internet/main/newsroom/meetings/past-meetings/ct_index202. FSIS provided this information during the March 2010 public meeting on traceback activities.

FSIS will instruct EIAOs to consider the following:

1. Was the supplier a sole supplier?
2. Was the supplied product beef manufacturing trimmings, coarse ground, or another raw ground beef component?

3. Are there data (e.g., testing results) to indicate that contamination likely did not occur at the receiving establishment?
4. Did the supplier send part of the same lot that was used to produce the positive product to another establishment?

If the answer to all of these questions is yes, FSIS will instruct EIAOs to inform the District Office that there is evidence that adulterated product is in commerce.

Instructions to FSIS field personnel to conduct traceback from the grinder or bench trim establishment will include asking a series of questions designed to identify all source materials and potential suppliers of beef components used as source materials in the production of the sampled lot of ground beef or bench trim. When finalized, these instructions will be available on the FSIS website where the public may access the information.

Comment: While the proposed changes to the recall policy address product from a sole-source supplier, two consumer groups encouraged FSIS to continue to work towards developing improved traceback procedures for product from multiple suppliers.

Response: As is explained above, FSIS intends to further explore if analyzing unopened packages will assist FSIS to effectively identify suppliers of STEC positive products. Any such methodology likely would consider whether the grinding or

bench trim establishment has its own verification program that includes testing of these source materials.

Comment: An industry organization commented that FSIS should verify that grinders maintain accurate recordkeeping, so that FSIS can identify the actual supplier of the contaminated product. This commenter stated that grinders need to maintain information that links the supplier of the raw materials to the sampled lot. This commenter also stated that the Agency should routinely verify that grinders maintain adequate records rather than wait until conducting a traceback investigation.

Response: Inspection program personnel collect information about the source materials and about the suppliers at the time they sample ground beef or bench trim at official establishments. Additionally, FSIS has made available compliance guidelines, Sanitation Guidance for Beef Grinders, that provides examples of good recordkeeping for grinders and includes recommendations that they maintain information about suppliers of source materials used in the manufacture of ground beef. The compliance guideline may be accessed at the following link:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index.

Finally, FSIS intends to publish a proposed rule to specify the information concerning suppliers and source materials that

establishment and retail grinders would be required to maintain. Should this rule become final, FSIS would issue instructions to inspectors to verify that establishments maintain required records.

Comment: One industry organization commented that recall determinations should be made after intensive investigations are carried out by the establishment where the positive result occurred and by FSIS. In addition, the organization recommended that the Agency's recall policy include a provision for FSIS and an establishment to agree on what product would be implicated by a positive finding before the sample is even taken. The commenter stated that many recent recalls resulted not from the failure to hold any product, but from the failure to hold all the implicated product.

Response: Establishments are now required to maintain control of all product that FSIS samples for adulterants, including ground beef that FSIS samples and tests for E. coli O157:H7 and beef manufacturing trimmings that FSIS samples and tests for STEC organisms (77 FR 73401; Dec. 10, 2012). Therefore, FSIS verifies that establishments maintain control of raw beef product that FSIS samples and tests for STEC organisms.

Establishments are responsible for defining the sampled lot. FSIS has informed establishments that they should have a supportable basis for determining the microbiological

independence of one production lot of product from another, particularly when same source materials may be included in multiple product lots. In the "Compliance Guideline For Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers," FSIS has recommended that establishments define their lots so that if a positive result is found from one lot, the product in other lots is microbiologically independent and is not implicated.

In the guideline, FSIS goes on to explain that when FSIS requests that establishments recall product, FSIS looks at several factors to determine the scope of a recall, including the establishment's processing and sanitation procedures, and whether there is any finished product reincorporated into fresh product (rework). In these guidelines, FSIS has recommended that establishments consider all these factors when defining a lot.

Comment: One industry organization commented that FSIS should take samples from product that is routinely manufactured and representative of the establishment's process. For instance, the commenter stated that if the grinder is making ground beef and routinely uses bench trim, then FSIS should sample and test ground product from bench trim.

Response: Consistent with the instructions in Directive 10,010.1, FSIS field personnel randomly select a day, shift, and

time within the sampling timeframe to collect samples from all shifts the establishment operates. These procedures provide for random FSIS sampling of the product and ensure that FSIS samples and tests all types of product the establishment produces.

Compliance Guideline for STEC Sampled-and-Tested Claims for Boneless Beef Manufacturing Trimmings

Comment: Industry organizations asked whether all labels that will carry the sampled-and-tested claim need to be submitted separately to FSIS. Additionally, the organizations asked how long it takes to receive label approval with this sampled-and-tested claim.

Response: All labels bearing STEC sampled-and-tested claims need to be submitted to FSIS. The Office of Public Health Science and various staffs in the Office of Policy and Program Development will review these labels. Because reviews of these labels will involve Agency staffs besides the Labeling and Program Delivery Staff, the reviews will probably take longer than those for other types of labels bearing special claims. As FSIS explained in the May 7, 2012 Federal Register, as part of the label review process, FSIS will verify that the establishment submitted evidence that demonstrates that the establishment's HACCP measures related to the adulterant STEC organisms are effective in reducing the pathogen to non-detectable levels, and that the results of the establishment's

sampling and testing demonstrate that those HACCP measures are effective (77 FR 26725). The Agency will try to ensure that the approval process is as timely as possible.

Comment: An industry organization suggested that FSIS develop labeling guidance based on the intended use of a product that contains beef manufacturing trimmings. The commenter stated that if the raw beef manufacturing trimmings have tested positive or presumptive-positive for E. coli O157:H7 and are diverted to be cooked, the beef manufacturing trimmings should be labeled "for cooking only."

Response: FSIS reviews labels bearing instructional statements such as "for cooking only" and verifies that establishments use such labels appropriately (i.e., for product going to another Federal establishment).

It is important to recognize that a "for cooking only" label is not sufficient to move adulterated product to another establishment for cooking or other full lethality treatment (e.g., high pressure processing or irradiation). Such product is adulterated and would need to move to other Federal establishments under company control.

Comment: A consumer group suggested that FSIS require, on a label bearing a sampled-and-tested claim, a statement that further clarifies that the claim does not mean that the labeled beef manufacturing trimmings are free of E. coli O157:H7.

Response: These sampled-and-tested claims on labels are not intended for use on product sold directly to consumers. FSIS would only approve labels with these claims if they include the relevant material facts; that is, a statement of limited use such as "not for sale at retail." Industry is aware of the limitations of the labeling terms or statements used regarding STEC organisms, and thus further explanation is not necessary.

Comment: One industry organization commented that the labeling was not feasible or practical. This commenter stated that printing out a label with the full sampled-and-tested claim and placing production lot information on each label would be costly. The organization requested that FSIS consider alternatives. For example, the commenter stated that information contained on the label could be included in sales receipts or other records received from the supplier without label approval.

Response: These labeling claims are voluntary, not required. If an establishment finds the claims to be costly or impractical, they will not use them. As is explained above, sampled and tested claims need to be submitted to FSIS for review before use on labels. Therefore, an establishment could not print sampled or tested claims that FSIS had not reviewed and approved on sales receipts or other records.

Compliance Guideline for Establishment Sampling of Beef Trimmings for Shiga Toxin-producing E. coli (STEC) or for Virulence; High-Event Periods (HEPs)

Comment: An industry association recommended that the Agency provide criteria for establishments that produce fewer than 50,000 pounds of beef manufacturing trimmings per day. One consumer group stated that, because FSIS based its HEP criteria on establishment data that already exists, FSIS should periodically review and revise its criteria, as appropriate, on the basis of industry data and performance. Another consumer asked whether the Agency would consider higher than 5 percent positive samples to be indicative of a problem in the establishment.

Response: The HEP guidance will be most useful to beef slaughter establishments that manufacture 50,000 pounds or more of beef manufacturing trimmings daily. Such establishments are likely to conduct sufficient verification testing on same source materials to be able to determine whether a HEP occurred. Through FSAs and outbreak investigations, FSIS has found that these establishments typically sample every combo bin or grouping of combo bins so that all product is subject to testing. Testing at this level is sufficient to determine whether a HEP occurred. Small volume establishments are unlikely to conduct sufficient verification testing to reliably

detect the occurrence of a HEP. Through FSAs and outbreak investigations, FSIS has found that these establishments typically sample once per day or once per week. This testing frequency would most likely not detect a HEP. However, the document includes some general guidance concerning verification testing that small volume establishments will find useful and discusses, in general terms, ways for smaller volume establishments, including those that produce less than 50,000 pounds per day, to define HEPs.

When FSIS conducts traceback verification activities at establishments that do not have their own HEP criteria, FSIS will use the Agency HEP criteria in the guidance discussed above to determine whether establishments are taking appropriate actions to keep adulterated product out of commerce during a HEP. If establishments set their own appropriate HEP criteria, FSIS will also assess whether establishments are taking appropriate actions to keep adulterated product out of commerce during a HEP, based on the establishments' HEP criteria.

The Agency is concerned about beef manufacturing trimmings (including those that tested negative) and primal and subprimal products produced during the HEP when the percent positive is greater than 5 percent with a high degree of statistical confidence. If an establishment defines a HEP based on a percent positive over 5 percent, it will need to have strong

support for its HEP. For example, if an establishment analyzes for more or broader indicators than those typically used to screen for E. coli O157:H7 and the six adulterant non-O157 STEC, the establishment may be able to support a HEP based on a higher percent positive. The establishment may be able to show that it is screening for additional non-O157 STEC. Therefore, the establishment may identify more HEPs in its production based on its testing than other establishments. If an establishment does not have strong support for a HEP over 5 percent, FSIS will not use the establishment's criteria in its assessment.

To develop recommendations for identifying HEPs, FSIS examined data collected in 2010 by FSIS inspection personnel from the top 33 slaughter establishments, based on production volume (heads slaughtered). Based on the results, FSIS selected a target of 5 percent. FSIS did not want to define HEP criteria that would be more rigorous than those of a large number of establishments and, therefore, did not select a lower target. Based on its analysis of outbreak-related recalls and the HEP criteria that establishments and FSIS used to identify the HEPs that led to these recalls, FSIS determined that the 5 percent target was sufficient to identify situations in which significant problems in slaughter dressing operations occurred that led to insanitary conditions. FSIS did not select a higher target (e.g., 10 percent) because, again based on the analysis

of outbreak-related recalls, a higher target would not be sufficient to identify such situations.

FSIS intends to assess the effectiveness of its new traceback procedures and to assess establishment HEP criteria again in the future if necessary to ensure that the criteria remain effective in preventing illness and remain useful to establishments. For example, if new, more sensitive screening test methods or new real time confirmation test methods become available, and establishments begin using them, FSIS will assess establishment results and changes in establishment HEP criteria to determine whether to change the FSIS HEP criteria.

Comment: An industry organization asked whether the occurrence of a HEP would cause sampled-and-tested labels to be rescinded.

Response: FSIS may decide to rescind a label if it determines that the occurrence of the HEP rendered the label incorrect, and the product misbranded. FSIS would consider all circumstances before rescinding a label.

Executive Order 13175

The policy discussed in this notice does not have Tribal Implications that preempt Tribal Law.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis

of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, audiotape, etc.) should contact USDA's Target Center at (202) 720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer

interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at http://www.fsis.usda.gov/News_&_Events/Email_Subscription/. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC: August 8, 2014.

Alfred V. Almanza,

Administrator.

[FR Doc. 2014-19141 Filed 08/12/2014 at 8:45 am; Publication Date: 08/13/2014]